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|  |   |    |   | Application Number       | 09/825,533           |
|  |   |    |   | Filing Date              | April 2, 2001        |
|  |   |    |   | First Named Inventor     | Michael R. Hufford   |
|  |   |    |   | Art Unit                 | 3693                 |
|  |   |    |   | Examiner Name            | Martin A. Gottschalk |
| Sheet  | 1 | of | 2 | Attorney Docket Number   | 31886-705.201        |

| U.S. PATENT DOCUMENTS |                          |  |                                |  |   |
|-----------------------|--------------------------|--|--------------------------------|--|---|
| Examiner<br>Initials* | Cite<br>No. <sup>1</sup> | Document Number                          | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|                       |                          | Number-Kind Code <sup>2</sup> (if known) |                                |  |   |
|                       | 1.                       | US 2002/0143595 A1                       | 10/03/2002                     | Frank et al.                                       |   |
|                       | 2.                       | US 2003/0194704 A1                       | 10/16/2003                     | Penn et al.  |   |
|                       | 3.                       | US 5,412,769                             | 05/02/1995                     | Maruoka et al.                                     |   |

| FOREIGN PATENT DOCUMENTS |                          |   |                                |  |   |                |
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| Examiner<br>Initials*    | Cite<br>No. <sup>1</sup> | Foreign Patent Document   | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines,<br>Where Relevant Passages<br>Or Relevant Figures Appear | T <sup>6</sup> |
|                          |                          | Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known) |                                |  |   |                |
|                          | 4.                       | None  |                                |  |   |                |

Continued on the next page with more references.

|                       |  |                    |  |
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| Examiner<br>Signature |  | Date<br>Considered |  |
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| NON PATENT LITERATURE DOCUMENTS |                       |   |                |
|---------------------------------|-----------------------|---|----------------|
| Examiner Initials*              | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|                                 | 5.                    | Copy of non-final office action mailed February 19, 2009 in connection with U.S. Patent Application No. 11/844,632.   |                |
|                                 | 6.                    | HUFFORD, et al. Collecting reliable and valid real-time patient experience data. Drug Information Journal. 2001; 755-765.   |                |
|                                 | 7.                    | HUFFORD, et al. Correspondence between paper and electronic visual analog scales among adult asthmatics. Invivodata. November 9, 2001.  |                |
|                                 | 8.                    | Invivodata, Inc. Insights. Third Issue. July 2001.  |                |
|                                 | 9.                    | Invivodata. Comparing electronic and paper diary data. Invivodata. November 26, 2001.   |                |
|                                 | 10.                   | Invivodata. Guaranteed patient compliance. Insight into patient behavior. Reduced study risks. July 2001.   |                |
|                                 | 11.                   | Invivodata. Innovations in Clinical Trial Technologies. Schedule for Seminar. 2001.   |                |
|                                 | 12.                   | Invivodata. Prove it - your drug's performance beats the competition. Date?   |                |

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